

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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9528 '03 JAN 17 A7:34
Establishment of Medical Device User Fee Rates for Fiscal Year 2003 and
Interim Procedures; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a correction notice that appeared in the **Federal Register** of January 10, 2003 (68 FR 1469). The document corrected a notice that appeared in the **Federal Register** of November 21, 2002 (67 FR 70228), which announced the rates and interim procedures for medical device user fees for fiscal year (FY) 2003. The November 21, 2002, document was inadvertently published with confusing language regarding the fee that must be paid by a small business that submits a 510(k) premarket notification for FDA review during FY 2003. The document intended to state that all 510(k)s submitted for FDA review during FY 2003 are subject to a standard fee of \$2,187, and that all submitters who are subject to a fee, including a small business, are required to pay this fee. This document corrects the error in the correction notice.

ADDRESSES: Persons with access to the Internet may obtain further information on the Medical Device User Fee and Modernization Act of 2002 at <http://www.fda.gov/cdrh/mdufma> or <http://www.fda.gov/cber/mdufma/mdufma.htm>.

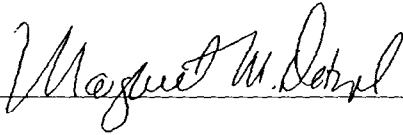
FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management and Systems (HFA-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4427.

SUPPLEMENTARY INFORMATION: In FR Doc. 03-494, appearing in the **Federal Register** of January 10, 2003, the following correction is made:

1. On page 1469, in the second column, at the bottom of the page, item 3 is revised to read

"On page 70229, in table 1, in the fourth column, in the last row, correct 'None in FY 2003' to read '2.1871'."

Dated: 1/16/03
January 16, 2003



Margaret M. Dotzel,
Assistant Commissioner for Policy

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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